510(k) Summary Pursuant to 21 CFR 807.92

Sponsor:	Pioneer Surgical Technology, Inc. (RTI Surgical, Inc.) 375 River Park Circle Marquette, MI 49855 USA Contact: Bethany Byman Phone: (906) 226-4803 Fax: (906) 226-4459 Prepared: March 19, 2014
Trade name:	Streamline OCT Occipito-Cervico-Thoracic System
Common name:	Posterior Occipito-Cervico-Thoracic System
Classification:	Class II per §888.3050 Spinal Interlaminal fixation orthosis
Product Codes/ Panel:	KWP Panel Code 87
Predicates:	Pioneer Streamline Occipito-Cervico-Thoracic (OCT) System (K121725) Exactech Gibralt Occipital Spine System (K110197/ K121877) Synthes Cervifix/Axon (K991089/K023675) Nex-Link Spinal Fixation System (K031985) DePuy Mountaineer OCT Spinal System (K110353) NuVasive Vuepoint OCT System (K093319)
Description:	The Streamline OCT Occipito-Cervico-Thoracic System consists of a variety of rods, hooks, polyaxial pedicle screws, high-angle pedicle screws, locking caps, occipital bone screws, occipital plates and connecting components used to build an occipito-cervico-thoracic spinal construct. The purpose of this submission is to add components to the system.
Materials:	The system components are manufactured from medical grade ASTM F136 titanium alloy and ASTM F71537 cobalt chromium alloy. Medical grade titanium alloy and cobalt chromium alloy may be used together.
Pre-Clinical Performance Data:	The subject system was evaluated per ASTM F1717 Static and Dynamic Compression Bending and Torsion Testing and compared to legally marketed predicate systems. Also, ASTM F1798 testing was performed to evaluate the interconnection mechanisms and subassemblies used in the worst-case spinal construct. Testing demonstrated that the device is as safe, as effective and performs as well as or better than predicate systems.

Intended Use:	When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3), the Streamline OCT Occipito-Cervico-Thoracic System is intended for: degenerative disc disease (as defined by neck or back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture/ dislocation, atlanto/axial fracture with instability, occipito-cervical dislocation, deformities or curvature, tumors, pseudoarthrosis, and revision of previous cervical and upper thoracic spine surgery. The occipital bone screws are limited to occipital fixation only. The use of the pedicle screws (standard and high angle) is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. The pedicle screws are not intended for use in the cervical spine. The hooks, connectors, and rods are also intended to provide stabilization to promote fusion following reduction of fracture/ dislocation or trauma in the cervical/ upper thoracic (C1-T3) spine. The Streamline OCT System can also be linked to FDA cleared pedicle screw systems (e.g., Quantum Spinal Fixation System, Streamline MIS Spinal Fixation System or Streamline TL Spinal System) using connectors.
Technological Characteristics:	The subject and predicate systems are overall similar in: - Intended use - Basic design: rod-based with screw/hook/plate anchors and connecting components - Materials: Titanium alloy and cobalt chromium alloy - Sizes: dimensions comparable to predicates - Sterilization and cleaning methods - Performance: equivalent mechanical test results The fundamental scientific technology of the subject system is the same as predicate devices. There are no significant differences between the Streamline OCT System and the predicate devices which would adversely affect the use of the product.
Substantial Equivalence:	This submission supports the position that the subject system is substantially equivalent to previously cleared pedicle screw systems based on comparison of indications for use, intended use, materials, technological characteristics, and pre-clinical performance testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 19, 2014

Pioneer Surgical Technology, Inc.
Ms. Bethany Byman
Regulatory Affairs Associate II
375 River Park Circle
Marquette, Michigan 49855

Re: K133374
Trade/Device Name: Streamline OCT Occipito-Cervico-Thoracic System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: February 03, 2013
Received: February 04, 2013

Dear Ms. Byman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent D Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K133374

Device Name: Streamline OCT Occipito-Cervico-Thoracic System

Indications: When intended to promote fusion of the cervical spine and occipito-cervico thoracic junction (occiput-T3); the Streamline Occipito-Cervico-Thoracic (OCT) System is intended for: degenerative disc disease (as defined by neck or back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture/ dislocation, atlanto/axial fracture with instability, occipito-cervical dislocation, deformities or curvature, tumors, pseudoarthrosis, and revision of previous cervical and upper thoracic spine surgery. The occipital bone screws are limited to occipital fixation only. The use of the pedicle screws (standard and high angle) is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. The pedicle screws are not intended for use in the cervical spine. The hooks, connectors, and rods are also intended to provide stabilization to promote fusion following reduction of fracture/ dislocation or trauma in the cervical/ upper thoracic (C1-T3) spine. The Streamline OCT System can also be linked to FDA cleared pedicle screw systems (e.g., Quantum Spinal Fixation System, Streamline MIS Spinal Fixation System or Streamline TL Spinal System) using connectors.

Prescription Use ___√___ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Colin O'Neill

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133374